

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**CHARLESTON DIVISION**

IN RE: ETHICON, INC.  
PELVIC REPAIR SYSTEMS  
PRODUCT LIABILITY LITIGATION

MDL No. 2327

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THIS DOCUMENT RELATES TO ALL CASES  
AND TO:

Jo Beth Huskey, et al. v.  
Johnson & Johnson, et al.  
Case No. 2:12-cv-05201

Tonya Edwards, et al. v.  
Johnson & Johnson, et al.  
Case No. 2:12-cv-09972

**PRETRIAL ORDER # 133**  
(Defendants' Motion to Deem Requests for Admissions Admitted)

Pending before the court is Defendants' Motion to Deem Requests for Admissions Admitted, or Alternatively, to Compel. (ECF No. 1017). Plaintiffs filed a response in opposition to the motion, (ECF No. 1048), and the undersigned conducted a telephonic hearing on August 5, 2014. Having fully considered the issues, the court **DENIES** the motion, without prejudice to Defendants to reassert the motion in the future should circumstances change.

On November 1, 2013, Defendants served all of the Plaintiffs in this multidistrict litigation with 138 requests for admissions ("RFAs"), "focused exclusively on the regulatory history of TVT products and PROLENE® Polypropylene Mesh." (ECF No. 1019 at 1). The RFAs were accompanied by fifty one documents, including various letters

sent to Ethicon from the Food and Drug Administration (“FDA”), portions of annual reports, parts of a package insert, and sections from 510(k) filings. (ECF No. 1019-1). None of the letters were produced by the FDA during the course of discovery, nor were any of the documents obtained from other third-parties, or the Plaintiffs. Rather, all of the documents came from Defendants’ file cabinets and computers. The RFAs asked Plaintiffs to (1) admit the genuineness of the documents; (2) admit that the documents included certain statements; and (3) admit the truth of various facts based upon information contained in the documents. Plaintiffs objected to the RFAs on a variety of grounds, all of which Defendants argue are without merit. Consequently, Defendants ask the court to deem the RFAs admitted, or in the alternative, to compel Plaintiffs to serve supplemental responses that comply with Federal Rule of Civil Procedure 36.

Rule 36 provides: “A party may serve on any other party a written request to admit, for purposes of the pending action only, the truth of any matters within the scope of Rule 26(b)(1) relating to (A) facts, the application of law to fact, or the opinions about either; and (B) the genuineness of any described documents.” Fed.R.Civ.P. 36(a)(1). The objectives of Rule 36 are explained in the Advisory Committee Notes to the 1970 amendment to the Rule as follows:

Rule 36 serves two vital purposes, both of which are designed to reduce trial time. Admissions are sought, first to facilitate proof with respect to issues that cannot be eliminated from the case, and secondly, to narrow the issues by eliminating those that can be.

First, and foremost, the undersigned denies Defendants’ motion because the RFAs at issue seek admissions that serve neither of the above-stated purposes. All of the RFAs deal with marketing clearance of TVT products and PROLENE® Polypropylene Mesh under the FDA’s 510(k) process. The presiding district judge has already ruled that

evidence related to the 510(k) process, and the FDA's clearance of mesh products under that process, is excluded because such evidence does not go to the efficacy of the medical devices and because of its potential to mislead and confuse the jury.<sup>1</sup> Consequently, even if all of the requests for admissions were admitted, Defendants would be precluded from using them at trial.

Moreover, the undersigned has an additional reservation with the RFAs in that they are, to a large extent, merely a pathway by which Defendants circumvent their obligation under Federal Rules of Evidence 901 and 902 to authenticate exhibits that they hope to offer at trial. As Plaintiffs point out in their responses to the RFAs, they have never seen the originals of the documents, did not generate the documents, and never had control over them; therefore, they can neither admit nor deny the genuineness of the documents. Equally as important, the documents were not obtained from third-parties through a formal discovery process, nor were they accompanied with an affidavit or certification prepared by a custodian under Rule 902. Certainly, no one would suggest that Plaintiffs have an obligation under Rule 36 to take the steps necessary to authenticate Defendants' exhibits in order to answer the RFAs. Thus, in the absence of some corroborating evidence of genuineness that meets Rule 901 or 902, and is supplied by Defendants or was previously produced in the case, Plaintiffs' reluctance to admit the genuineness of the documents is both understandable and reasonable. If the genuineness of the documents cannot be established, then the remaining requests, which are based on the documents, are likewise suspect.

Having determined that the RFAs will not be deemed admitted and more complete responses will not be compelled at this time, the undersigned acknowledges

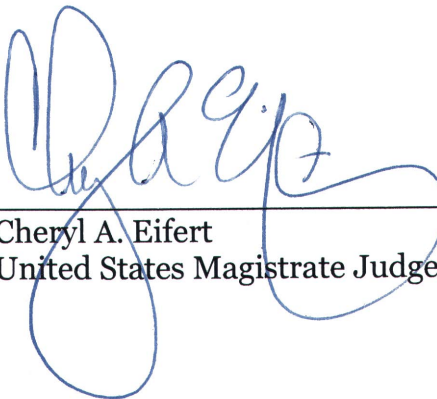
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<sup>1</sup> See *Huskey v. Ethicon, et al.*, Case No. 2:12-cv-05201, at ECF No. 223.

Defendants' stated intention to pursue their position that evidence of 510(k) clearance should be presented at trial. For that reason, the parties are **ORDERED** to meet and confer to determine whether any or all of the documents attached to the RFAs can be stipulated as being genuine and authentic.

The court **DIRECTS** the Clerk to file a copy of this order in 2:12-md-2327, **2:12-cv-05201, and 2:12-cv-09972** and it shall apply to each member related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action number 2:14-cv-24378. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at <http://www.wvsd.uscourts.gov>.

**ENTERED:** August 6, 2014



Cheryl A. Eifert  
United States Magistrate Judge